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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/701,883

11/05/2003

Nabil L. Muhanna

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Holland & Hart, LLP (LANX, Inc.)
Intellectual Property Department
P.O. Box 8749
Denver, CO 80201-8749

EXAMINER

PRONE, CHRISTOPHER D

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

10/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/701,883	Applicant(s) MUHANNA ET AL.	
	Examiner CHRISTOPHER D. PRONE	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-13,15,16,18,20-23,26-30,41-45 and 48-52 is/are pending in the application.
- 4a) Of the above claim(s) 3,11-13,16,22,23,27-30 and 41-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-10,15,18,20,21,26 and 48-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/23/10 has been entered.

Status of Claims

Claims 1-4, 6-13, 15, 16, 18, 20-23, 26-30, 41-45, and 48-52 are pending of which claims 3, 11-13, 16, 22, 23, 27-30, and 41-45 are withdrawn.

Priority Date

The earliest support for the elected embodiment of this application is in provisional application 60476075 filed on 06/05/03.

Claim Rejections - 35 USC § 103

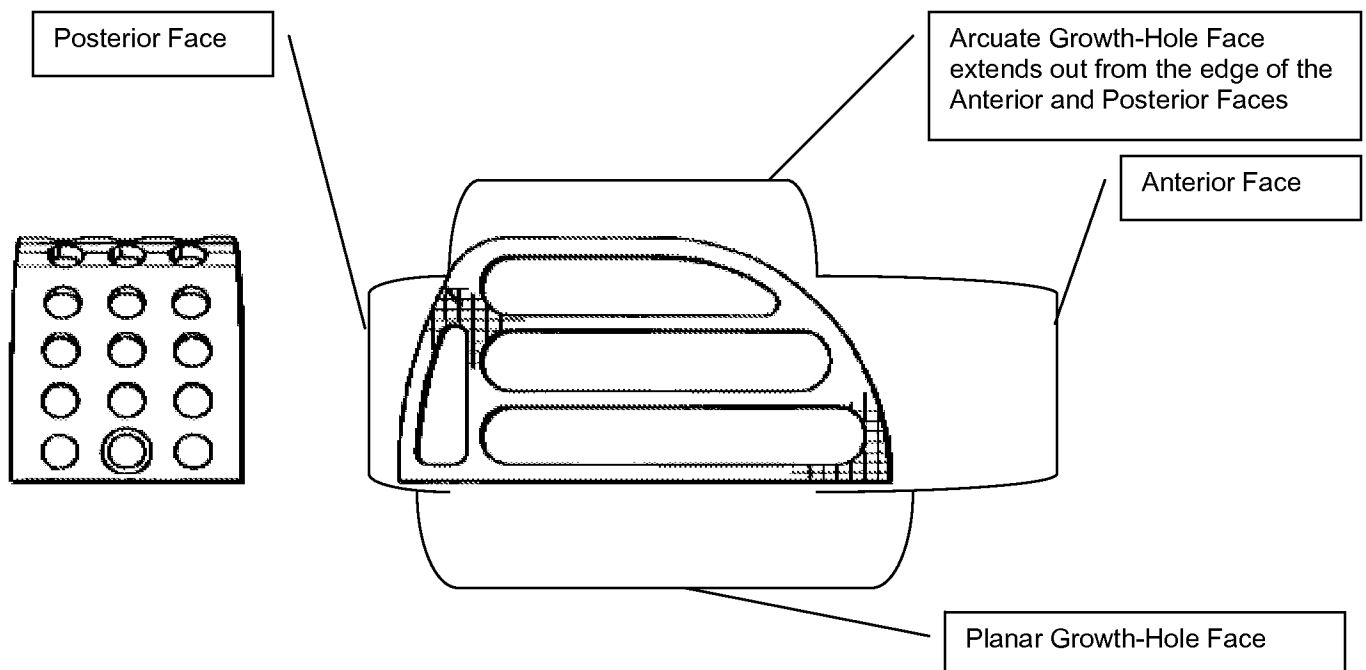
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1, 2, 4, 6-10, 15, 18, 20, and 50-52 is rejected under 35 U.S.C. 103 as being unpatentable over Michelson United States Patent 6,890,355 in view of Brantigan United States Patent 5,192,327 and Viart et al United States Patent 6,682,562 B2.

Michelson discloses a metal vertebral body replacement comprising a body 300, nonparallel top and bottom surfaces (shown best in figures 15-17) having a plurality of through holes and continuous grooves 314 and protrusions (5:62-65), two growth hole faces 310 (planar) and 312 (curved) having 4 through holes 319 and a curves anterior face 304. Michelson further discloses use of a second identical implant for insertion along side the first 300".

In response to the amended language a marked up figure is included below to demonstrate how the arcuate growth-hole face extends outward.



In regards to claim 2 the grooves on the top surface extend completely through a portion of the top surface.

In regards to claims 48-50 Michelson discloses a plurality of grooves that extend perpendicular to the posterior surface. The first groove on the top is clearly not aligned in the same plane as with the last groove on the bottom.

However Michelson fails to disclose a groove on the top surface that extends through the anterior and posterior faces and that the teeth are aligned generally orthogonal to the grooves.

Brantigan discloses a spinal implant comprising a body having a top surface with projections and grooves that extend generally along the top surface of an implant extending through the anterior and posterior faces in the same field of endeavor for the purpose of providing the maximum surface contact thereby securing the implant to the implant site.

Viart discloses a plurality of spinal implant comprising a body having a top surface with varying projections and grooves that are made up of a plurality of teeth aligned with an edge orthogonal to the grooves formed between them in the same field of endeavor for the purpose of providing more distinct contact points (teeth) engaging the surrounding implant site

In view of Michelson's lack of specific disclosure for its textured upper surface it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide continuous grooves and protrusions on the top surface as taught by Brantigan and to form the protrusions out of a plurality of teeth with edges aligned

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orthogonal to the grooves as taught by Viart with the device of Michelson in order to provide an implant with continuous grooves and protrusions having increased contact with the surrounding body that extend through the anterior and posterior surfaces which will secure the implant to the implant site.

In regards to the amended language requiring grooves with width capable of receiving an insertion tool, this is being considered language of intended use. This application is directed at an implant not a tool or a kit for inserting an implant. In view of this and the infinite number of tools that could be used to grasp the implant, it is obvious that the width of the grooves of the modified implant above would be able to be gripped by an insertion tool.

Claim 21 is rejected under 35 U.S.C. 103 as being unpatentable over Michelson in view of Brantigan and Viart as applied to claims 1, 2, 4, 6-10, 15, 18, 20, and 48-50 above and further in view of United States Patent Paul et al 6,143,033.

The combination of Michelson, Brantigan, and Viart discloses the invention substantially as claimed being described supra. However, combination fails to disclose making his device from the bone comprising the medullary cavity.

Paul teaches the use of an implant made from bone comprising medullary cavity in the same field of endeavor for the purpose of using natural materials that the body will accept and grow into.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the bone material taught by Paul with the device of

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Michelson as modified by Brantigan and Viart in order to provide an implant made from all natural materials.

Claim 26 is rejected under 35 U.S.C. 103 as being unpatentable over Michelson in view of Brantigan and Viart as applied to claims 1, 2, 4, 6-10, 15, 18, 20, and 48-50 above and further in view of Wagner et al. United States Patent 5,306,309.

The combination of Michelson, Brantigan, and Viart discloses the invention substantially as claimed being described above. However, the combination fails to disclose making his device from a plurality of bonded layers.

Wagner teaches the use of an implant comprising a base metal having layers bonded to its outer surface in the same field of endeavor for the purpose enhancing the implants material properties. (6:13-40)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of Michelson as modified by Brantigan and Viart out of a plurality of layers as taught by Wagner in order to provide an implant with enhanced durability or porosity.

Claims 48 and 49 are rejected under 35 U.S.C. 103 as being unpatentable over Michelson United States Patent 6,890,355 in view of Brantigan United States Patent 5,192,327

Michelson discloses a metal vertebral body replacement comprising a body 300, nonparallel top and bottom surfaces (shown best in figure 17) having a plurality of

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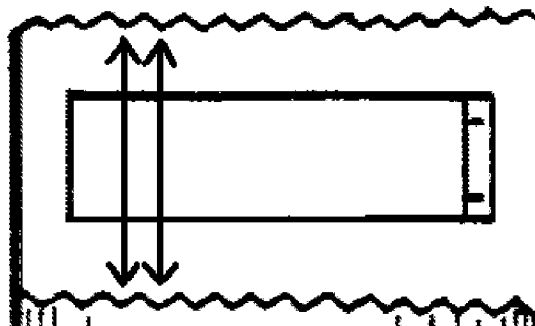
through holes and continuous grooves 314 and protrusions (5:62-65), two growth hole faces 310 (planar) and 312 (curved) having 4 through holes 319 and a curved anterior face 304. Michelson further discloses use of a second identical implant for insertion along side the first 300".

In regards to claim 2 the grooves on the top surface extend completely through a portion of the top surface.

In regards to claims 48-50 Michelson discloses a plurality of grooves that extend perpendicular to the posterior surface. The first groove on the top is clearly not aligned in the same plane as with the last groove on the bottom.

However Michelson fails to disclose a groove on the top surface that extends through the anterior and posterior faces and that the grooves on the upper surface are unaligned with the grooves on the lower surface.

Brantigan discloses a spinal implant comprising a body having a top surface with projections and grooves that extend generally along the top through the anterior and posterior faces wherein the projections and grooves are unaligned (see figure below) in the same field of endeavor for the purpose of securing the implant to the implant site.



In view of Michelson's lack of specific disclosure for its textured upper surface it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide continuous grooves and protrusions on the top surface that are orientated opposite the grooves and protrusions on the bottom surface as taught by Brantigan with the device of Michelson in order to provide an implant with continuous grooves and protrusions having increased contact with the surrounding body better securing the implant to the implant site.

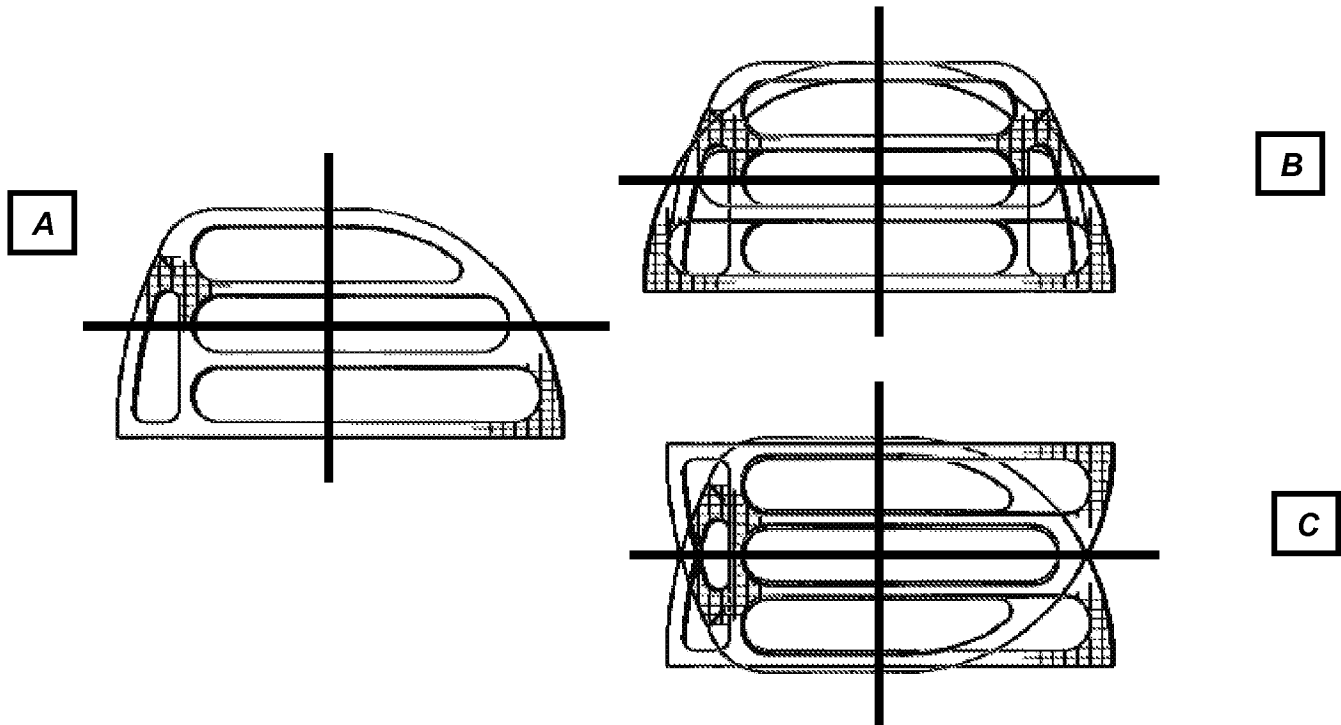
In response to the amended language requiring the arcuate growth-hole face to extend outward and the grooves to comprise a width capable of receiving an insertion tool, this has been addressed above in the other Michelson combination.

Response to Arguments

Applicant's arguments filed 12/23/09 have been fully considered but they are not persuasive. The applicant argues that Michelson fails to disclose an arcuate growth-hole face extending outward. This is not persuasive and has been addressed in the figure included above. The applicant further argues that Michelson fails to disclose serrations and at least one elongated groove in the top of the body that extends through the anterior face and the posterior face of the body in which teeth forming the serrations providing openings generally orthogonal to the at least one elongated groove. This is not persuasive because the combination relies on the teachings of Brantigan disclosing the use of grooves that extend through the anterior and posterior faces and Viart disclosing making the serrations out of a plurality of separate teeth to

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read on this claim language. The applicant further argues that implant is not asymmetrical when viewed from above. The following figure is included to show that the implant of Michelson is asymmetrical when viewed from the top. Figure A is the original top view of the implant. Figure B includes a top view of the implant that has been flipped horizontally and superimposed over the original top view. Figure C includes a top view of the implant that has been flipped vertically and superimposed over the original top view.



Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. PRONE whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday through Fri 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738

/Christopher D Prone/

/Corrine M McDermott/

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Supervisory Patent Examiner, Art Unit 3738